**REMARKS/ARGUMENTS**

Claims 1-11 were in the application. In the last office action, claim 11 was rejected under 35 U.S.C. § 112 for failing to point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner objected to the use of the word "short" as indefinite.

Claims 1-11 were rejected on art.

Turning first to the Section 112 rejection, the phrase "short catheter" is one of art. According to the Infusion Nursing Standards of Practice (November/December 2006), a short catheter is one that is less than or equal to 3 inches (7.5 cm) in length. See the attached Advisory Opinion, Intravenous Infusion Therapy/Venipuncture: The Role of the Licensed Practical Nurse. Hence the phrase to which the Examiner has objected is not indefinite. "Short" when used to describe a catheter refers to a specific and definite range of lengths. For the foregoing reasons, withdrawal of the Section 112 rejection is respectfully requested.

Dealing now with the cited art, claims 1-4 and 7-11 have been rejected under 35 U.S.C. 103(a) as obvious over Purdy et al. in view of Rossi et al. This rejection is respectfully traversed for the following reasons.

Purdy discloses a trapping device which is bent toward the use position of the needle, while the needle remains in the horizontal axis of the device. The withdrawal of the needle inside the cage causes the trapping device to return to its original position,

which results in the trapping of the needle inside the cage. The needle however still remains in its initial alignment with the horizontal axis of the device. There is no inclination of the needle in Purdy.

Rossi discloses a trapping device with the needle mounted on a slider, the slider being used for the withdrawal of the needle. In order to move the needle from its initial position, the device includes a deflector (13, 16 and 22), the deflector acting on the slider during its backward displacement. Without the deflector, the slider could not induce the displacement of the needle from its axis, since it is in translation on the cage. There is however no suggestion of the combination of elemenets recited in claim 1. The bending of a blade that is perpendicular to the needle in order to move the needle from its initial axis, and which pushes the needle towards a wall of the cage in order to maintain the needle trapped inside the cage is neither displayed nor suggested by the combination of Rossi and Purdy. Those references, if combined, would suggest either the use of a deflector, or the maintenance of the needle in its initial axis.

Claim 1 recites, inter alia,

> the blade is at rest and traversed freely by the needle when the needle is pushed in the distal direction, and so that the blade stops the needle and is bent by the needle when the needle is drawn in the proximal direction beyond a given axial position, so that the bent blade inclines the needle and applies a return force to the needle which tends to force the needle back in the distal direction

until the puncture end comes up against a wall of the chamber.

The deflector in Rossi does not function as does the blade recited in claim 1. Rossi's deflector is not "traversed freely by the needle" but moves with it as a single assembly.

In view of the above, it is respectfully submitted that claim 1 and each of claims 2-11 which depend from claim 1 are not rendered obvious by the combination of Purdy and Rossi, and are, therefore, patentable.

Claims 5 and 6 have been rejected under 35 U.S.C. 103(a) as obvious over Purdy et al. in view of Rossi et al. in further view of Woehr et al.

Woehr does not teach how to induce the displacement of the needle from its initial axis in order to trap it inside a cage. Woehr addresses a technical issue similar to one with which Purdy is concerned, namely, the provision of a way to trap the needle using a device that is deformed during use of the needle, and that returns to a its original position when the needle is withdrawn. Hence, applicant respectfully submits that Woehr has no adverse effect on the patentability of claims 5 and 6.

Claim 1 has been amended to correct an obvious formal error wherein the term "chamber" was incorrectly used instead of "cage".

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance. Early and favorable action is earnestly solicited.

An unpaid fee required to keep this case alive may be charged to deposit account 06-0735.

Respectfully Submitted,

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**OPINION: INFUSION THERAPY /VENIPUNCTURE BY LICENSED PRACTICAL NURSES**
**DATE APPROVED: 7/95**
**REVISED DATE: 5/96, 5/97, 10/98, 5/99, 1/00, 6/29/01, 07/02, 2006, 7/07, 3/08**
**ORIGINATING COMMITTEE: SCOPE OF PRACTICE COMMITTEE**

# ADVISORY OPINION
# INTRAVENOUS INFUSION THERAPY/VENIPUNCTURE: THE ROLE OF THE LICENSED PRACTICAL NURSE

This Advisory Opinion has four parts: 1) The basic competencies of all LPN's, 2) Additional skills learned by an organized course of instruction, 3) Education and competency for additional skills, 4) Skills not considered within the scope of a LPN.

The role of the LPN in intravenous infusion therapy is determined and assigned by the RN.

I. The following competencies are within the scope of practice of *all* Licensed Practical Nurses provided they have received training and education in their core curriculum or in an organized course of instruction and are validated by the employer as competent.

A. Calculation of correct infusion rates for un-medicated intravenous infusions.

B. Regulation of rates for un-medicated IV fluids (ie: D5W, saline solution, and Ringers solution).

C. Addition of un-medicated IV solution to existing peripheral-short and peripheral midline IV therapy.

D. Inspection of IV sites and reporting of signs of complications such as infiltration, infection, or malfunction of the infusion.

E. Providing for peripheral-short*, peripheral-midline**, and central IV catheter site care, including cap and dressing changes.

F. Measuring and recording intake and output related to IV medications, including fluids and irrigations.

G. Observation of client's responses to IV therapy, therapeutic nursing interventions, and identifying and reporting adverse reactions.

H. Discontinuation of peripheral catheters used for intravenous therapy, including peripheral-short and peripheral midline. Excludes peripheral external jugular catheters

*Definition of a peripheral-short catheter: According to the Infusion Nursing Standards of Practice (November/December 2006), a peripheral-short is one that is less than or equal to 3 inches (7.5 cm) in length.

**Definition of a midline catheter: According to the Infusion Nursing Standards of Practice (November/December 2006), a midline catheter is one that is between 3 inches (7.5 cm) and 8 inches (20 cm) in length and categorized as "peripheral-midline."

II. If delegated to do so by an RN, **it is within** the Scope of Practice for a Licensed Practice Nurse to perform the following additional tasks, AFTER they have met the requirements specified in section III.

A. Inserting peripheral-short catheters for infusion (may draw blood immediately post-insertion for laboratory specimens).

B. Routine flushes with saline or heparinized saline, including peripherally inserted central catheters (PICC)* and central lines. This includes routine flushes with the completion of medication administration.

C. Administer, monitor and discontinue specified premixed/admixture medications into peripheral-short peripheral-midline sites only.

1. Premixed solutions are solutions that are

a. mixed, labeled and signed by the pharmacist, OR

b. commercially prepared.

2. Admixture medications are in powder form and attached to a solution ready to be mixed.
3. A current list of approved solutions and medications will be kept on file by the agency or employer.

*Definition of PICC: a Peripherally Inserted Central Catheter

III. Current Licensed Practical Nurses may perform the tasks listed in Section II after they have met the following requirements:

A. The Licensed Practical Nurse has satisfactorily completed an instructional program on intravenous therapy and medication skills, during their Arizona LPN core curriculum or in an organized course of instruction.

B. Practical nurses by endorsement may:

1. Successfully complete a LPN IV and Medication Skills course of instruction in another state and show evidence of that coursework and;
2. Demonstrate competency to employer.

C. The minimum 45 hour course of instruction is to include, but not limited to:

1. Anatomy and Physiology of skin and vascular systems.
2. Client evaluation, equipment (use and malfunctions), and peripheral site selection.
3. Infection control/Universal precautions/needle safety devices.
4. Peripheral-short venipuncture technique and discontinuation.
5. Technique for flushing all types of intravenous lines.

6. Principles of IV therapy, including medication administration, care and maintenance of peripheral-short and peripheral-midline, PICC, and central line catheters.
7. Fluid and electrolytes/homeostasis.
8. Complications of IV therapy, local, mechanical and systemic.
9. Nursing care responsibilities and documentation.
10. Pharmacology/calculations and nursing implications for selected IV fluids and medications.
11. Board of nursing statutes/rules/advisory opinion/policies and procedures, including delegation/supervision responsibilities.

D. Documentation of satisfactory completion of a minimum 45-hour instructional program, successful completion of the competency test, and supervised practice are on file with the agency/employer and a copy given to the LPN to be retained as verification of completion. The supervised practice is recommended to include a minimum of 5 successful venipunctures. It is the employer's responsibility to validate the LPN's competency to provide infusion care.

E. Written policies and procedures are maintained by the agency/employer.

F. Recommended course developer qualifications: a registered nurse with a BSN and two years of experience in nursing and with experience in adult education.

G. Recommended instructor qualifications: BSN with a minimum of two years practice in nursing as a registered nurse with substantial direct clinical experience in IV therapy.

IV. Skills that are NOT considered within the scope of a LPN.

A. Administration of:

1. Parental nutrition (PN)
2. Intralipids
3. Blood, blood products or plasma expanders
4. Antineoplastic drugs
5. Investigative or research medications
6. Direct IV push except flushes
7. IV Medications for procedural sedation/anesthesia
8. Drugs which require close RN monitoring, assessment, or interpretation of data, or titration.
9. IV for contrast
10. Systemic lytics: thrombolytics, fibrinolytics

B. Initiate, program, administer solutions or medications, repair, or discontinue the following devices:

1. PICC and central lines
2. Implanted infusion pumps
3. Intrathecal, epidural, intraosseous, umbilical, or ventricular reservoirs.
4. Peripheral external jugular catheter.

C. Inserting, repairing, or discontinuing arterial and central venous catheters, including PICC lines.

D. Access/remove a non-coring needle from an implanted subcutaneous port.

**Rationale**

To provide the nursing community with guidelines to clarify the LPN's role regarding intravenous therapy and venipuncture.

**References**


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